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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. _____ (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca LP, AstraZeneca UK Limited, and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively, "DRL" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208541 ("ticagrelor ANDA") filed by Defendant with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of AstraZeneca's BRILINTA® (ticagrelor) drug product prior to expiration of AstraZeneca's U.S. Reissue Patent No. RE46,276 ("the '276 patent") that is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for BRILINTA®.

PARTIES

2. AstraZeneca is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail against serious diseases, including treatments for cardiovascular diseases.

3. Plaintiff AstraZeneca LP, the holder of New Drug Application ("NDA") No. 022433 for BRILINTA® (ticagrelor), is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. Plaintiff AstraZeneca UK Limited is a company operating and existing under the laws of the United Kingdom, with its principal place of business at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, United Kingdom CB2 0AA. AstraZeneca UK Limited is the owner of the '276 patent. Defendant specifically directed a letter dated June 11, 2019 with the headings "Re: Notice of Paragraph IV Certification Re: Dr. Reddy's Laboratories,

Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Ticagrelor Tablets, 60 mg and 90 mg; U.S. Patent No. RE46,276" and "Detailed Factual and Legal Basis for Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Assertion of Invalidity, Unenforceability or Non-Infringement of U.S. Patent No. RE46,276") ("Notice Letter") to AstraZeneca UK Limited.

5. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP markets and sells BRILINTA® in this judicial district and throughout the United States. Defendant specifically directed the Notice Letter to AstraZeneca Pharmaceuticals LP.

6. On information and belief, DRL Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India. On information and belief, DRL Ltd., itself and through its affiliates and subsidiaries, including DRL Inc., formulates, manufactures, packages, and markets generic drug products for distribution in the District of New Jersey and throughout the United States.

7. On information and belief, DRL Inc. is a company organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, DRL Inc. is a wholly-owned subsidiary of DRL Ltd. On information and belief, DRL Inc. is a U.S. agent of DRL Ltd.

8. On information and belief, DRL Ltd., itself and through its U.S. agent, DRL Inc., formulates, manufactures, packages, and markets generic drug products for distribution in the District of New Jersey and throughout the United States.

9. On information and belief, Defendant developed the proposed generic product that is the subject of the ticagrelor ANDA to seek regulatory approval from FDA to market and sell the proposed ANDA product throughout the United States, including within New Jersey.

10. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of the ticagrelor ANDA, Defendant will distribute and sell the generic product described in the ticagrelor ANDA throughout the United States and within New Jersey.

JURISDICTION AND VENUE

11. Each of the preceding paragraphs 1 to 10 is re-alleged and re-incorporated as if fully set forth herein.

12. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

14. On information and belief, venue is proper in the District of New Jersey for DRL Ltd. because it is an Indian corporation "not resident in the United States" that accordingly "may be sued in any judicial district" for venue purposes. 28 U.S.C. § 1391(c)(3); *see also In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018) (reaffirming the "long-established rule that suits against aliens are wholly outside the operation of all the federal venue laws, general and special." (quoting *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 714 (1972))).

15. On information and belief, venue is proper in the District of New Jersey for DRL Inc. because it is incorporated in New Jersey, and thus the District of New Jersey is the judicial district "where the defendant resides." 28 U.S.C. § 1400(b); *see also TC Heartland LLC v. Kraft*

Foods Grp. Brands LLC, 581 U.S. ____, 137 S. Ct. 1514, 1521 (2017) ("As applied to domestic corporations, 'reside[nce]' in § 1400(b) refers only to the State of incorporation.").

16. DRL is subject to specific personal jurisdiction in this District based on the filing of its ticagrelor ANDA with a Paragraph IV certification regarding the '276 patent. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762-63 (Fed. Cir. 2016).

17. As in *Acorda*, DRL "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at," on information and belief, this District and elsewhere. *Acorda Therapeutics*, 817 F.3d at 759.

18. DRL's "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Acorda Therapeutics*, 817 F.3d at 760.

19. As in *Acorda*, on information and belief DRL Ltd., alone and/or in concert with its agent, DRL Inc., "intends to direct sales of its drugs" into this District, among other places, "once it has the requested FDA approval to market them." *Acorda Therapeutics*, 817 F.3d at 758.

20. On information and belief, DRL Ltd., alone and/or in concert with its agent, DRL Inc., will engage in marketing of its proposed ticagrelor ANDA product in New Jersey, upon approval of its ticagrelor ANDA.

21. DRL's ANDA filing, including its Paragraph IV certification regarding the '276 patent at issue here, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities in this District by Defendant.

22. "[T]he minimum-contacts standard is satisfied by the particular actions [Defendant] has already taken—its ANDA filing[]—for the purpose of engaging in that injury-

causing and allegedly wrongful marketing conduct" in this District. *Acorda Therapeutics*, 817 F.3d at 760.

23. On information and belief, DRL Ltd. and DRL Inc. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

24. On information and belief, DRL Ltd. and DRL Inc. work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products in the District of New Jersey and throughout the United States.

25. On information and belief, DRL Ltd. and DRL Inc. acted in concert to develop the proposed generic product that is the subject of the ticagrelor ANDA to seek regulatory approval from FDA to market and sell the proposed ANDA product in the District of New Jersey and throughout the United States.

26. In the Notice Letter, DRL notified AstraZeneca UK Limited and AstraZeneca Pharmaceuticals LP that DRL had submitted its ticagrelor ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Through its agent located in New Jersey, DRL sent the Notice Letter from New Jersey to AstraZeneca in Delaware.

27. Further, on information and belief, DRL will manufacture, market, and/or sell within the United States the generic product described in the ticagrelor ANDA if FDA approval is granted. If the ticagrelor ANDA is approved, on information and belief the generic product would, among other things, be marketed and distributed in New Jersey, prescribed by physicians practicing in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

28. Furthermore, DRL has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of New Jersey courts through the assertion of counterclaims and through the filing of its own declaratory judgment actions. *See, e.g.*, *Dr. Reddy's Labs., Inc. et al. v. AstraZeneca AB et al.*, C.A. No. 1-18-cv-16057; *Celgene Corp. v. Dr. Reddy's Labs., Inc. et al.*, C.A. No. 3-18-cv-11269; *Celgene Corp. v. Dr. Reddy's Labs., Ltd. et al.*, C.A. No. 2-18-cv-06378; and *Sumitomo Dainippon Pharm. Co., Ltd. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 2-18-cv-02620.

29. This Court also has personal jurisdiction over DRL because, *inter alia*, DRL has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, DRL regularly and continuously transacts business within the state of New Jersey, including by selling pharmaceutical products in New Jersey, directly and/or through affiliates, and/or by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including New Jersey. On information and belief, DRL derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey.

30. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over DRL.

PATENT-IN-SUIT

31. On February 25, 2003, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 6,525,060 ("the '060 patent"), entitled "Triazolo(4,5-d)pyrimidine compounds." A true and correct copy of the '060 patent is attached hereto as **Exhibit A**. On January 17, 2017, the '060 patent was surrendered when the U.S. Patent and Trademark Office

duly and legally issued the '276 patent, a reissue of the '060 patent. A true and correct copy of the '276 patent is attached hereto as **Exhibit B**. The claims of the '276 patent are valid and enforceable. AstraZeneca UK Limited is the owner of the '276 patent by assignment and has the right to enforce it.

32. AstraZeneca LP is the holder of NDA No. 022433 by which FDA granted approval for the marketing and sale of ticagrelor tablets in 90 mg and 60 mg dosage strengths, to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome (ACS) or a history of myocardial infarction (MI). AstraZeneca markets ticagrelor tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "BRILINTA®." FDA's official publication of approved drugs, the Orange Book, includes BRILINTA® in 90 mg and 60 mg dosage strengths together with various patents listed as covering BRILINTA® (including the '276 patent).

INFRINGEMENT BY DEFENDANT

33. Each of the preceding paragraphs 1 to 32 is re-alleged and re-incorporated as if fully set forth herein.

34. In the Notice Letter, DRL notified AstraZeneca LP that it had submitted its ticagrelor ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

35. The Notice Letter states that DRL is seeking approval from FDA to engage in the commercial manufacture, use, and sale of generic ticagrelor tablets before the expiration of the '276 patent. On information and belief, DRL intends to engage in the commercial manufacture, use, and sale of its generic ticagrelor tablets after receiving FDA approval to do so.

36. In the Notice Letter, DRL notified AstraZeneca that its ticagrelor ANDA contained a "Paragraph IV certification" asserting that the '276 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of DRL's generic ticagrelor tablets.

37. This Complaint is being filed before the expiration of the forty-five days from the date AstraZeneca received the Notice Letter.

38. Pursuant to 21 U.S.C. 355(j)(2)(B)(ii), any notice letter containing a Paragraph IV certification must contain a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, is unenforceable, or will not be infringed." In Defendant's Notice Letter, Defendant admits that its ticagrelor ANDA product will contain ticagrelor and does not deny that the commercial manufacture, use, offer to sell, or sale of its proposed ticagrelor ANDA product will directly infringe or induce infringement of at least claims 1, 18, and 19 of the '276 if these claims are found not invalid.

39. For example, claim 18 of the '276 patent recites "[a] compound chosen from: [1*R*-[1α,2α,3β(1*R**,2*S**)5,β]]-3-[7-[[2-(3,4-Difluorophenyl)cyclopropyl]amino]-5-[(3,3,3-trifluoropropyl)thio]-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(hydroxymethyl)-cyclopentane-1,2-diol; and [1*S*-[1α,2α,3β(1*S**,2*R**),5β]]-3-[7-[[2-(3,4-Difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)-cyclopentane-1,2-diol." Exhibit B, col. 28, ll. 10-18.

40. Claim 19 of the '276 patent recites "[a]n oral pharmaceutical composition comprising [1*S*-[1α,2α,3β(1*S**,2*R**),5β]]-3-[7-[[2-(3,4-Difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)-cyclopentane-1,2-diol in combination with a pharmaceutically acceptable diluent, adjuvant, and/or carrier suitable for

oral administration, wherein said oral pharmaceutical composition is in the form of a tablet, pill, capsule, liquid, powder, or granule." Exhibit B, col. 28, ll. 19-28.

41. In its Notice Letter, Defendant admits that the chemical name for ticagrelor is [1S-[1α,2α,3β(1S*,2R*),5β]]-3-[7-[[2-(3,4-Difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)-cyclopentane-1,2-diol. Defendant further admits that its proposed ticagrelor ANDA product will be a tablet for oral use.

COUNT I (INFRINGEMENT OF THE '276 PATENT)

42. Each of the preceding paragraphs 1 to 41 is re-alleged and re-incorporated as if fully set forth herein.

43. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '276 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

44. By filing ANDA No. 208541, Defendant has necessarily represented to the FDA that Defendant's ticagrelor ANDA Products have the same active ingredient as BRILINTA®, have the same dosage form and strength as BRILINTA®, and are bioequivalent to BRILINTA®.

45. On information and belief, Defendant is seeking approval to market Defendant's ticagrelor ANDA Products for the same approved indications as BRILINTA®.

46. AstraZeneca received the Notice Letter from Defendant, purporting to include a Notice of Certification for ANDA No. 208541 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '276 patent.

47. Defendant thus has actual knowledge of the '276 patent.

48. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendant has infringed at least one claim, including at least claims 1, 18, and 19, of the '276 patent by

submitting, or causing to be submitted, to the FDA, ANDA No. 208541 seeking approval to manufacture, use, import, offer to sell or sell Defendant's ticagrelor ANDA Products before the expiration date of the '276 patent. Upon information and belief, the products described in ANDA No. 208541 would infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claims 1, 18, and 19, of the '276 patent.

49. On information and belief, Defendant's ticagrelor ANDA Products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claims 1, 18, and 19, of the '276 patent under at least one of 35 U.S.C. § 271(a), (b), (c), and/or (g).

50. On information and belief, Defendant will manufacture, market, import, use, sell and/or offer to sell Defendant's ticagrelor ANDA Products in the United States in connection with ANDA No. 208541 upon approval.

51. If Defendant's marketing and sale of Defendant's ticagrelor ANDA Products prior to expiration of the '276 patent and all other relevant activities are not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca respectfully prays that this Court grant the following relief:

A. A judgment that the claims of the '276 patent are not invalid, not unenforceable, and are infringed by Defendant's submission of its ticagrelor ANDA, and that Defendant's making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's generic ticagrelor tablets will infringe the '276 patent.

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Defendant's ticagrelor ANDA shall be a date which is not earlier than the latest

expiration date of the ’276 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

C. An order permanently enjoining Defendant, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendant’s generic ticagrelor tablets until after the latest expiration date of the ’276 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

D. Damages or other monetary relief to AstraZeneca if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Defendant’s generic ticagrelor tablets prior to the latest expiration date of the ’276 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

E. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: July 23, 2019

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiffs hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy is the subject of the following pending actions:

- *AstraZeneca LP, et al. v. HEC Pharm Co. Ltd., et al.*, Civil Action No. 2:19-cv-14737-CCC-MF (D.N.J.).

Plaintiffs further hereby certify that the matter in controversy was previously the subject of the following action in the District of New Jersey: *AstraZeneca LP, et al. v. HEC Pharm Co. Ltd.*, et al, Civil Action No. 15-8082-PGS-TJB (D.N.J.). The matter was closed on February 4, 2016 pursuant to a Notice and Order of Voluntary Dismissal.

DATED: July 23, 2019

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